CARE FERTILITY

Patient safety incident response policy (PSIRF)

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Purpose

This policy sets out Care fertility's approach to developing and delivering effective processes for responding to patient safety incidents, including any and all events where "things don't go right first time" for the purpose of learning and improving patient safety and experience.

Scope

This policy relates to incident responses conducted for the purpose of **learning and improvement.** It applies to incidents; investigations following freedom to speak up events, and; events leading to product recall. This list is not exhaustive. All events where things don't go right first time and there are opportunities for learning fall within the scope of this policy.

There is no remit to apportion blame or determine liability, preventability or cause of death in a response conducted for the purpose of learning and improvement. Other processes exist for that purpose and are outside the scope of this policy, such as human resources investigations, professional standards investigations, inquests and criminal investigations. Information from a patient safety response can be shared with those leading other investigations (HR investigations for example), but these processes should not influence the remit of a patient safety incident response.

Regulatory background

Care has a statutory duty imposed by the **Human Fertilisation and Embryology Authority** (HFEA) to

- have procedures for reporting and investigating incidents and for sharing the outcome of investigations including final conclusions and recommendations for preventive and corrective actions to the HFEA in accordance with Directions 0011 - Reporting adverse incidents and near misses.
- have procedures in place to enable the recall from distribution any product that may be related to a serious adverse event or reaction.

Those Care clinics with a licence from the **Human Tissue Authority** (HTA) have a statutory duty to report serious adverse events and reactions (SAERs) relating to HTA licensable activity to the HTA. See Human application serious adverse event and reaction (SAEARs) reporting | Human Tissue Authority (hta.gov.uk).

Those Care clinics registered with the **Care Quality Commission** (CQC) are required to notify CQC of all incidents that affect the health, safety and welfare of people who use services. See Regulation 18: Notification of other incidents - Care Quality Commission (cqc.org.uk) and to exercise a Duty of Candour in the event of notifiable safety incidents.

Clinics providing NHS commissioned fertility treatment have a contractual obligation to adopt[1] NHS England's Patient Safety Incident Response Framework. On the basis that the PSIRF supersedes HFEA guidance, this policy primarily reflects PSIRF principles while acknowledging the requirements of HFEA and HTA.

Care clinics have a duty to report If someone has died or been injured because of a work-related accident to the HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR).

Adverse incidents involving medical devices, faulty products and/or suspected side effects to medicines should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card scheme.

The Patient Safety Incident Response Framework

Root cause analysis (RCA) is cited by HFEA as the appropriate methodology for incident investigation but NHS England has concluded that this approach to learning from patient safety

[1] Small providers are not required to implement PSIRF – only adopt the principles.

incidents prompts simple linear cause-and-effect analysis that has consistently failed to deliver anticipated benefits.

The PSIRF differs from RCA in

- recognising that outcomes in complex systems like healthcare result from the interaction of **multiple factors** and that learning should not focus on uncovering a single (root) cause, but instead explore **all relevant contributory factors**.
- using tools that support exploration of multiple interacting contributory factors rather than forcing a single analytical pathway.
- being based on SEIPS (Systems Engineering Initiative for Patient Safety)

The four key aims of the PSIRF are

- compassionate engagement and involvement of those affected by patient safety incidents
- application of a range of system-based approaches to learning from patient safety incidents
- considered and proportionate responses to patient safety incidents and safety issues
- supportive oversight focused on strengthening response system functioning and improvement.

Responses to patient safety incidents are based on a systems-based investigations. **Responses do not take a 'person-focused' approach** centred on the actions or inactions of people, or 'human error'.

Care's patient safety culture

Care supports and encourages all staff to be confident to speak up when things go wrong without fear of blame. The culture is promoted as follows:

- all staff have access to Datix and are encouraged to report whenever something doesn't go right first time;
- all newly employed staff are provided with induction training that emphasises the value of reporting when things don't go right first time;
- analysis of the frequency of incident reporting and benchmarking between Care clinics nationally provides an insight into each individual Care clinic's level of openness and transparency: where an individual Care clinic submits fewer than expected reports as a proportion of their activity than other clinics in the group this informs activity to support and encourage an open and transparent culture;
- reporting of any and all events is integrated through Datix (e.g. patient safety incidents, safeguarding, complaints, and Freedom to Speak Up reports) enabling triangulation of information and ensuring risks are identified and responded to in the most effective way;
- Care has well-established procedures to ensure that all relevant incidents are escalated to HFEA, CQC, MHRA, HSE and commissioning ICBs as required. The effectiveness of reporting is overseen during routine HFEA inspections and ICB quality review meetings.

Care is committed to promoting a culture of openness and learning.

Patient safety partners

The Human Fertilisation and Embryology Authority (HFEA) is Care's primary patient safety partner. HFEA gathers and collates information on all incidents including no harm and near miss incidents across all UK fertility providers and disseminates learning as required. Patient safety information is also collated from other regulators (MHRA and NICE for example) and professional bodies (RCOG, RCPath, BFS).

Integrated data gathering and documentation in Datix allows trend analysis and shared learning across Care clinics nationally and internationally. Patient safety alerts and associated actions are also documented on Datix ensuring implementation of required improvements when learning is shared by safety partners.

Addressing health inequalities

Care is committed to using data to identify any disproportionate risk and or harm to patients with protected characteristics. A review of feedback cross referenced to protected characteristics is conducted annually and is disseminated at clinic level and reported to the Care Board.

Care's system-based rather than 'person focused' investigation approach and the scope of Care's safety investigation remit as set out in this policy aim to support a just culture for all staff

Engaging and involving patients, families and staff following a patient safety incident

The PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. It supports the development of an effective patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents (including patients and staff). This involves working with those affected by patient safety incidents to understand and answer any questions they have in relation to the incident and signpost them to support as required.

When engaging with or involving those affected by patient safety incidents in an Investigation it is Care's policy that

- A meaningful apology is given alongside a commitment to address the affected person(s) questions and concerns.
- The approach to engagement should be individualised and flexible depending on the affected person(s) individual and changing practical, physical, and / or emotional needs.
- Timing of engagement is sensitive to the individual person(s) needs in consideration that some people can feel they are being engaged and involved too slowly or too quickly or at insensitive times. Timing of engagement should be led by the affected person(s).
- Those affected are treated with respect and compassion.
- The principles of statutory and professional Duty of Candour must be upheld
- Guidance and information should be clear, understandable and not assume any prior understanding.
- Those affected should be 'heard' and have the opportunity to be listened to and share their experience. They will all have their individual perspective of what happened and each one is valid in building a comprehensive picture to support learning. Importantly, the opportunity to be listened to is also part of restoring trust and repairing relationships between organisations and staff and patients.
- The approach to investigation should be collaborative and open and aim to provide answers.
- Subjectivity should be accepted - no one truth should be prioritised over others. Patients, families, and healthcare staff are all credible sources of information.
- Investigations should strive for equity. The opportunity for learning should be weighed against the needs of those affected by the incident.

Patient safety incident response planning

The HFEA generally imposes a requirement for patient safety incident investigation (PSII) where incidents are graded as B or A according to the HFEA's own categorisation criteria.

Incidents meeting the threshold of the NHS Never Events criteria (2018) or its replacement, and deaths thought more likely than not to have been due to problems in care (i.e. incidents meeting the learning from deaths criteria for patient safety incident investigation) also require a locally-led PSII.

Beyond these requirements, PSIRF supports incident responses that maximise learning and improvement, rather than being based on arbitrary and subjective definitions of harm. In accordance with this principle, it is Care's policy to investigate low and no harm (HFEA grade C) incidents where there is opportunity for learning and or where trend analysis of these incidents suggests they occur frequently and impact on patient care, safety and or experience. Near miss incidents are investigated based on the anticipated likely impact should the incident have failed to be avoided as a result of chance or good fortune.

For more information see Guide to responding proportionately to patient safety incidents, patient safety incident response standards and the PSIRF preparation guide

Resources and training to support patient safety incident response

Care's Director of Governance is designated learning response lead with responsibility for PSIRF oversight. They undergo training as recommended in the patient safety incident response standards.

Care's Quality and Governance team provide resource and are responsible for identifying and allocating additional resources to investigation and undergo training as follows:

- Patient safety syllabus level 1: Essentials for patient safety
- Patient safety syllabus level 2: Access to practice

Our patient safety incident response plan

As an independent provider of NHS commissioned fertility services, Care is required to adopt but not implement PSIRF. The ICB advising Care on PSIRF adoption did not recommend development of an incident response plan.

Responding to and reporting patient safety incidents

Patient safety incident response and reporting procedures are documented in Corp CS 46 Incident Reporting, Management and Procedure Policy.

Oversight roles and responsibilities

Care's Director of Governance is responsible for PSIRF oversight. Care aims to focus on enabling and monitoring improvement in the safety of care. Responding to a patient safety incident for learning is recognised as an active strategy for continuous improvement, not a reflection of something having been done wrong.

Oversight of the effectiveness of the patient safety incident response systems and processes is informed by information from the following pre-existing data sources

- incident severity, type and frequency reports extracted from Datix
- complaints type and frequency reports extracted from Datix
- post consultation and treatment patient feedback
- clinical and regulatory audit findings of non-conformance reports extracted from Datix
- information from staff surveys
- information shared following freedom to speak up investigations
- the findings and feedback from biennial HFEA inspections.

The results of Care's quality improvement activities are reported to Care's Governance and Care Hub for Quality (GCHQ) quarterly and to the Care Board twice yearly. Information is disseminated to clinics at bi-monthly Operational and Governance meetings and is reviewed at clinic level at monthly Clinical Governance meetings.

Appendix 1: Definitions

Incident - An Incident is defined as an event or circumstance which causes or has the potential to cause any of the following:

- Harm, either physical or mental, to an individual which can be a patient, staff member or visitor
- Financial loss to an individual or to CARE
- Damage to the property of an individual or to CARE
- Disruption to services provided by CARE
- Damage to the reputation of CARE
- Non-compliance with regulations or CARE Policy

Incidents are divided into types as follows

- A **clinical incident** is an event that happens to a patient that causes, or could have caused harm to the patient, as a direct consequence of their clinical or medical care.
- A **non-clinical incident** is an event that causes, or could have caused harm that may affect anyone (including staff, patients, visitors, contractors etc.) or to CARE.
- The categories/subcategories of incidents are listed in the DATIX User guides.

Incident severity - the **actual** outcome of an incident (not what could have happened) is categorised according to the level of harm caused as follows:

- No Harm
- Low Harm
- Moderate Harm
- Severe Harm
- Catastrophic/Death
- **Near miss** – A near miss is an unplanned event that did not result in injury, illness or damage but had the potential to do so. HFEA definition is an occurrence that, but for luck, skill or judgment, would in all probability have become an adverse incident.
- **Never event** - Is defined by the Department of Health as a "serious, largely preventable patient safety incident that should not occur if the available preventable measures have been implemented by healthcare providers". The management of Never Events is undertaken in line with the Never Events Policy Framework and the Never Events List Never Events policy and Framework

HFEA Definition of adverse incident

An 'adverse incident' is any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre. This includes serious adverse events, serious adverse reactions, breaches of confidentiality, anomalies or deficiencies in recording of consent, and ovarian hyperstimulation syndrome (OHSS) that has a severity grading of severe or critical.

The 1990 HF&E Act (as amended) defines an incident as:

a. 'any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application and which, in relation to a donor of gametes or a person who receives treatment services or non-medical fertility services—

i) might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions, or

ii) might result in, or prolong, hospitalization or illness, or

b. any type of gametes or embryo misidentification or mix-up'.

RIDDOR – Reporting of Injuries, Diseases and Dangerous Occurrences Regulations. a RIDDOR report is only required when the accident is work related, and it results in a reportable injury. See Types of reportable incidents - RIDDOR - HSE

HTA (Human Tissue Authority) definition of incident

Serious Adverse Event (SAE): Any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of tissue or cells intended for human application and which, in relation to a donor of tissue or cells intended for human application or a recipient of tissue or cells
(a) might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions; or
(b) might result in, or prolong, hospitalisation or morbidity.

Serious Adverse Reaction (SAR): An unintended response, including a communicable disease, in a donor of tissue or cells intended for human application or a recipient of tissue or cells, which may be associated with the procurement or human application of tissue or cells and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.